

EXHIBIT A

Excerpts from the transcript of the July 17, 2019 deposition of
Jay W. Heinecke, M.D

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

AMARIN PHARMA, INC., et al.,

Plaintiffs,

vs.

HIKMA PHARMACEUTICALS USA INC.,
et al.,

Defendants.

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Case No.:

2:16-cv-02525-MMD-NJK

Consolidated with:

2:16-cv-02562-MMD-NJK

VIDEOTAPED DEPOSITION OF

JAY W. HEINECKE, M.D.

San Francisco, California

Wednesday, July 17, 2019

Reported by Stenographer

MARY J. GOFF

CSR No. 13427

Job No. 162979

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Videotaped Deposition of
JAY W. HEINECKE, M.D., Volume I, taken on behalf of
Plaintiffs, at Winston & Strawn LLP, 101 California
Street, San Francisco, California 94111, beginning
at 8:04 a.m. and ending at 4:12 p.m., on July 17,
2019, before MARY J. GOFF, California
Certified Shorthand Reporter No. 13427.

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APPEARANCES:

For Plaintiffs

COVINGTON & BURLING
BY: CHRISTOPHER SIPES, ESQ.
ERIC SONNENSCHNEIN, ESQ.
One City Center
850 Tenth Street, NW
Washington, DC 20001

For Defendants

Winston & Strawn
BY: EIMERIC REIG-PLESSIS, ESQ.
101 California Street
San Francisco, California 94111

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APPEARANCES CONTINUED:

For Dr. Reddy's Laboratories Defendants
Windells Marx Lane & Mittendorf
BY: CONSTANCE HUTTNER, ESQ.
Attorney at Law
One Giralda Farms
Madison, New Jersey 07940
(appeared via phone)

ALSO PRESENT: Joseph T. Kennedy, Amarin EVP, GC
Videographer:
Marcus Majers

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BY MR. REIG-PLESSIS --

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1	San Francisco, California	10:20	1	With me is my colleague, Eric	08:04
2	July 17, 2019	10:20	2	Sonnenschein; and Joe Kennedy of Amarin Pharmaceuticals.	08:04
3	8:04 a.m.	10:20	3	MR. REIG-PLESSIS: I'm Eimeric Reig of Winston & Strawn, on behalf of the Hikma Defendants and the witness.	08:04
4	10:20		4	THE VIDEOGRAPHER: And has anyone joined on the phone yet?	08:04
5	THE VIDEOGRAPHER: Good morning. This is the start of media labeled No. 1 of the video recorded deposition of Dr. Jay W. Heinecke, in the matter of Amarin Pharma, Inc., et al, versus Hikma Pharmaceuticals USA Inc., et al., in the United States District Court, District of Nevada, Case No.: 2:16-cv-02525-MMD-NJK; Consolidated with: 2:16-cv-02562-MMD-NJK.	08:02	5	MR. REIG-PLESSIS: I don't think so.	08:04
6			6	MR. SIPES: Okay. Great.	08:04
7	This deposition is being held at Winston & Strawn, 101 California Street, San Francisco, California, on July 17, 2019, at approximately 8:04 a.m.	08:03	7	JAY W. HEINECKE, M.D., being first duly sworn or affirmed to testify to the truth, the whole truth, and nothing but the truth, was examined and testified as follows:	08:04
8			8	EXAMINATION	08:04
9			9	BY MR. SIPES:	08:04
10	My name is Marcus Majers. I'm the legal video specialist from TSG Reporting, Inc., headquartered at 747 Third Avenue, New York, New York. The court reporter is Mary Goff, in association with TSG Reporting.	08:03	10	Q Good morning. Thank you for coming in this morning.	08:04
11			11	Could you please state your name and spell it for the record?	08:04
12	Will all counsel present please introduce themselves.	08:04	12	A Yes. My name is Jay Walter Heinecke, HEINECKE; J A Y; Walter, W A L T E R.	08:04
13			13	Q And where do you reside?	08:04
14	MR. SIPES: Christopher Sipes of Covington & Burling LLP, on behalf of the Plaintiff.	08:04	14	A I reside in Seattle, Washington.	08:04
15			15	Q And you are currently employed?	08:04
16			16		
17			17		
18			18		
19			19		
20			20		
21			21		
22			22		
23			23		
24			24		
25			25		

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<p>1 A I'm currently provide by the University of 08:04 2 Washington. 08:04 3 Q And what is your work address? 08:04 4 A My work address would be the University of 08:05 5 Washington, 850 Republican Street, Seattle 98109. 08:05 6 Q Okay. Have you been deposed before? 08:05 7 A I have never been deposed as an expert 08:05 8 witness. 08:05 9 Q You have been deposed as a fact witness? 08:05 10 A As a what? 08:05 11 Q Have you been deposed as a fact witness? 08:05 12 Have you ever been deposed in any capacity? 08:05 13 A I have. 08:05 14 Q Okay. How many times? 08:05 15 A One time. 08:05 16 Q Okay. I will go through the rules. I 08:05 17 suspect you -- you know them, having been through 08:05 18 it. 08:05 19 But first, you understand that you are 08:05 20 under oath today and are required to answer my 08:05 21 questions truthfully? 08:05 22 A Yes. 08:05 23 Q If you don't understand a question, please 08:05 24 let me know and I will attempt to clarify it. 08:05 25 Otherwise, I will assume that you understood it; is 08:05</p>	<p>1 that fair? 08:05 2 A Yes. 08:05 3 Q This is not an endurance test. If at some 08:05 4 time you need a break, let me know and we'll try to 08:05 5 endeavor to find a good breaking point for you. 08:05 6 A Okay. 08:05 7 Q You understand that the court reporter is 08:05 8 taking down a transcript, so you'll need to answer 08:05 9 audibly with verbal responses? 08:05 10 A I do. 08:06 11 Q Also, you -- your counsel may from time to 08:06 12 time object, but you'll need to answer the 08:06 13 questions, if you understand them, unless you're 08:06 14 instructed not to answer by counsel. 08:06 15 Do you understand? 08:06 16 A I understand. 08:06 17 Q Is there any reason why you cannot give 08:06 18 complete and truthful testimony today? 08:06 19 A No, not that I'm aware after. 08:06 20 Q Okay. And as far as you're -- you don't 08:06 21 have any medical condition or medications that might 08:06 22 interfere with your ability to answer truthfully? 08:06 23 A No. 08:06 24 Q Let me hand to you three documents that 08:06 25 have been marked as Exhibits 1, 2, and 3 in the 08:06</p>
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<p>1 case. 08:06 2 (Exhibit 1 was marked for identification 08:06 3 and is attached to the transcript.) 08:06 4 (Exhibit 2 was marked for identification 08:06 5 and is attached to the transcript.) 08:06 6 (Exhibit 3 was marked for identification 08:06 7 and is attached to the transcript.) 08:06 8 A Okay. 08:06 9 Q (BY MR. SIPES) Do you recognize 08:06 10 Exhibits 1, 2, and 3 as the reports that you 08:06 11 prepared in this case? Since you have Exhibit 1 in 08:06 12 your hands, if you would turn to page 241 of 08:07 13 Exhibit 1, if you're looking for your signature. 08:07 14 A Thank you. 08:07 15 Q That -- that is your signature -- 08:07 16 A Yes -- 08:07 17 Q -- on page 241 of Exhibit 1? 08:07 18 A -- that's my signature on -- 08:07 19 Q And you -- why don't we deal with 08:07 20 Exhibit 1. 08:07 21 A You -- 08:07 22 Q You have got it in front of you. 08:07 23 A Yeah. Yeah. 08:07 24 Do I need to look at the signatures on the 08:07 25 other ones as well? 08:07</p>	<p>1 Q We can go through them one at a time, I -- 08:07 2 A Okay. 08:07 3 Q -- think is easiest. 08:07 4 A Fine. 08:07 5 Q And Exhibit 1 is the -- your opening 08:07 6 report -- 08:07 7 A Yes. 08:07 8 Q -- in this case, correct? 08:07 9 And you have signed it on or about 08:07 10 March 11 of 2019? 08:07 11 A Yes. 08:07 12 Q And you understand that you -- you signed 08:07 13 your expert report under penalty of perjury? 08:07 14 A Yes. 08:07 15 Q And did you endeavor to make what you 08:07 16 stated in your opening report -- and first of all, 08:08 17 is it all right if we refer to your -- Exhibit 1 as 08:08 18 your opening report? 08:08 19 A That's fine. 08:08 20 Q And did you endeavor to -- to make your 08:08 21 statements in Exhibit 1 to be as truthful and 08:08 22 accurate as possible? 08:08 23 A I endeavored to make the statements as 08:08 24 truthful and accurate as possible. 08:08 25 Q Are you aware of any errors or corrections 08:08</p>

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1	Q But the -- the not significant increase	09:13	1	THE COURT REPORTER: Wait.	09:14
2	was 2.5 percent --	09:13	2	A Excuse me. Yes.	09:14
3	A Yes.	09:13	3	Q (BY MR. SIPES) Okay. And -- now, the	09:14
4	Q -- over placebo in the high triglyceride	09:13	4	patients -- a person of ordinary skill in the art	09:14
5	group, correct; and it was 49.2 percent?	09:14	5	would also recognize --	09:15
6	A Yes.	09:14	6	THE COURT REPORTER: I'm sorry? The --	09:15
7	Q So it was many times larger in the very	09:14	7	what?	09:15
8	high triglyceride group, correct?	09:14	8	Q (BY MR. SIPES) Let me -- a person of	09:15
9	A Correct.	09:14	9	ordinary skill in the art in 2008 would also	09:15
10	Q Okay. So a person of ordinary skill in	09:14	10	recognize that patients who had high triglycerides,	09:15
11	the art is going to recognize that the fibrates	09:14	11	but also had high LDL-C, actually saw a decrease in	09:15
12	produced a -- a much larger and statistically	09:14	12	LDL-C that was statistically significant relative to	09:15
13	significant increase in LDL cholesterol in the very	09:14	13	placebo from fibrates, correct?	09:15
14	high triglyceride patient population and did not	09:14	14	MR. REIG-PLESSIS: Objection to form.	09:15
15	show even a statistically significant change in the	09:14	15	A Yeah, can you restate that, please?	09:15
16	high triglyceride pop -- patient population,	09:14	16	Q (BY MR. SIPES) A person of -- a person of	09:15
17	correct?	09:14	17	ordinary skill in the art in 2008 would understand	09:15
18	A In this particular study, correct.	09:14	18	from the 2004 TRICOR labeling that patients that had	09:15
19	Q Okay. And the clinical study in the	09:14	19	high triglycerides, but also had high LDL-C	09:15
20	TRICOR labeling would have been a clinical study	09:14	20	cholesterol, saw a decrease in LDL-C from TRICOR,	09:15
21	that was --	09:14	21	correct?	09:15
22	A Yes.	09:14	22	A Yes.	09:15
23	Q -- reviewed by FDA --	09:14	23	Q So a person of ordinary skill in March of	09:15
24	A Yes.	09:14	24	2008 would recognize that the effects of TRICOR can	09:15
25	Q -- correct?	09:14	25	vary depending on both the patient's LDL-C level and	09:15
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1	its triglyceride level, correct?	09:16	1	THE VIDEOGRAPHER: This marks the end of	09:16
2	MR. REIG-PLESSIS: Objection to form.	09:16	2	media file labeled No. 1. Off the record at	09:16
3	A Yeah, that's very specific. I think there	09:16	3	9:18 a.m.	09:17
4	could be a number of other factors that could	09:16	4	(A break was taken from 9:18 a.m. to	09:17
5	influence that conclusion.	09:16	5	9:30 a.m.)	09:17
6	Q (BY MR. SIPES) And what other factors	09:16	6	THE VIDEOGRAPHER: This marks the	09:29
7	might influence that conclusion?	09:16	7	beginning of media file labeled No. 2. Back on the	09:29
8	A Well, the underlying genetic disorder, for	09:16	8	record at 9:30 a.m.	09:29
9	example.	09:16	9	Q (BY MR. SIPES) Dr. Heinecke, let me ask	09:29
10	Q And would a person of ordinary skill in	09:16	10	you to turn to paragraph 137 of your rebuttal	09:29
11	the art believe that the patients with mixed	09:16	11	report.	09:29
12	dyslipidemia likely had a different underlying	09:16	12	MR. REIG-PLESSIS: That's Exhibit 2.	09:29
13	disorder than the patients with high triglycerides?	09:16	13	A Yes.	09:29
14	A Yes, that would be likely.	09:16	14	Q (BY MR. SIPES) In paragraph 137, you	09:29
15	Q Okay. And similarly, would a person of	09:16	15	state, Fibrates, niacin, Lovaza, EPANOVA, and Omtryg	09:29
16	ordinary skill in the art in 2008 understand that	09:16	16	were (and still are) all FDA approved to reduce	09:29
17	patients with very high triglycerides likely had a	09:16	17	triglycerides, including in the claimed patient	09:30
18	different underlying disorder than patients with	09:16	18	population with baseline levels of 500 milligrams	09:30
19	mixed dyslipidemia?	09:16	19	per deciliter or higher, correct?	09:30
20	A Yes, I believe that's correct.	09:16	20	A Yes.	09:30
21	Q Okay.	09:16	21	Q And that list of fibrates, niacin, Lovaza,	09:30
22	THE DEPONENET: Can we take a restroom	09:16	22	EPANOVA, and Omtryg, along with VASCEPA, is the full	09:30
23	break soon?	09:16	23	list of drugs approved by FDA presently to treat	09:30
24	MR. SIPES: Why don't we take a break.	09:16	24	very high triglycerides, correct?	09:30
25	A That sounds good. Thank you.	09:16	25	A I -- I don't know the answer to that.	09:30

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Q Okay. Are you aware of any drug approved by FDA to treat very high triglycerides, other than fibrates, niacin, Lovaza -- Lovaza, EPANOVA, Omtryg and VASCEPA?

A No.

Q Now, you state that those -- that, Fibrates, niacin, Lovaza, EPANOVA, and Omtryg were all FDA approved to reduce triglycerides, including in the claimed patient population with baseline levels of 500 milligrams per deciliter or higher.

Do you see that?

A Yes.

Q When you say "were," what time frame are you talking about?

A I know that during my time of taking care of patients with high triglycerides, that niacin was approved for that, and fibrates (phonetic) were approved.

I don't know the exact dates for the other drugs.

Q Okay. Is it your --

A You mentioned --

Q -- I'm sorry. I didn't want to cut you off. Would --

A Yeah. No. Excuse me.

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Q Is it your understanding that EPANOVA was approved by March of 2008?

MR. REIG-PLESSIS: Objection to form.

A I can't answer that question.

Q (BY MR. SIPES) Now, it's not your testimony sitting here today that EPANOVA is part of the prior art, correct?

A Could you -- could you define what you mean by "part of the prior art"?

Q Okay. Why don't we -- in your opening report --

A Yes.

Q -- on paragraph 18 --

MR. REIG-PLESSIS: It's Exhibit 1.

A Yes.

Q (BY MR. SIPES) -- Exhibit 1 --

A Yes. Thank you.

Q -- you note that you have been informed by counsel that March of 2008 is the date claimed for conception of the claimed inventions, correct?

A Where is that written --

Q It's --

A -- again?

Q -- actually at the top of page 8. It's the one sentence in -- in paragraph 18 of your

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opening report. Paragraph 18.

A 18. Okay. Yes.

Q So you understand -- and you don't dispute the March of 2008 conception date for the inventions at issue in this case, correct?

A I do not.

Q All right. So is it your understanding that for purposes of evaluating prior art, the critical date is March 2008?

A Yes, it is.

Q Okay. So going back to the list of medications for very high triglycerides that you have in your rebuttal report --

A Yes.

Q -- in paragraph 137, it is not your testimony -- is it your testimony that EPANOVA was known in the art prior to March of 2008?

A I can't recall the specific date that that was approved.

Q Okay. So --

A I would have to do further research --

Q Okay.

A -- on that point.

Q So sitting here today, you're not prepared to -- to testify that EPANOVA was known in the art

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prior to March of 2008?

A I'm trying to remember here. Well, since I can't claim that I know the exact date, I would have to agree with that.

Q And you do not rely on EPANOVA for purposes of your opinions on obviousness in this case, correct?

A If I knew the specific date of approval for the EPANOVA, I could answer that correctly.

Q Well, do you recall that you -- you used two different obviousness combinations in your opinions?

A Yes.

Q And one involved the drug Lovaza?

A Yes.

Q And the other involved the drug Epadel?

A Yes.

Q And EPANOVA is neither Epadel, nor Lovaza, correct?

A Correct.

Q Okay. So to the best of your recollection, are you relying on EPANOVA in your obviousness opinions in this case?

MR. REIG-PLESSIS: Objection to form. Do you mean objective indicia or premium fascia?

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<p>1 Q (BY MR. SIPES) In -- in your opening 09:35 2 report where you opined on the obviousness of the 09:35 3 invention, did you rely on EPANOVA in forming your 09:35 4 opinions? 09:35 5 A Since I can't remember the specific date, 09:35 6 I would have to do further research on that question 09:35 7 to answer that. 09:35 8 Q Okay. And similarly, sitting here today, 09:35 9 is it your opinion that Omtryg is prior art? 09:35 10 A Again, I don't remember the specific date 09:35 11 for that, and so I would have to research that 09:35 12 further in order to answer the question. 09:35 13 Q All right. And do you understand that 09:35 14 Omtryg is neither Lovaza, nor Epadel? 09:35 15 A Yes. 09:35 16 Q And you -- sitting here today, you're not 09:35 17 prepared to answer one way or the other as to 09:35 18 whether or not, in your opinions of obviousness 09:35 19 expressed in your opening report, you rely upon 09:35 20 Omtryg? 09:35 21 MR. REIG-PLESSIS: Objection to form. 09:35 22 A Could you be more specific about exactly 09:35 23 what you are referring to? 09:35 24 Q (BY MR. SIPES) You -- you recall in your 09:35 25 opening report, putting together opinions on 09:35</p>	<p>1 obviousness? 09:36 2 A Yes. 09:36 3 Q Okay. Do you -- okay. 09:36 4 Do you recall sitting here today whether 09:36 5 or not, in forming your opinion of obviousness that 09:36 6 you expressed in your opening report, you relied on 09:36 7 Omtryg as part of the prior art? 09:36 8 A You would have to refer me to the specific 09:36 9 point where I do that. 09:36 10 Q Okay. I -- I don't find it in your 09:36 11 opening report. But I'm not the master of your 09:36 12 opinions, which -- 09:36 13 A Yeah. 09:36 14 Q -- is why I asked. 09:36 15 A Okay. 09:36 16 Q So I take it sitting here today, you do 09:36 17 not recall relying on Omtryg in forming your 09:36 18 opinions of obviousness that you expressed in your 09:36 19 opening report? 09:36 20 A I do not recall that. 09:36 21 Q Okay. So let's turn to your opening 09:36 22 report, paragraph 18. 09:36 23 A Paragraph 18. 09:36 24 Q 18, yeah. You state, I have been asked by 09:36 25 counsel to offer my opinions regarding the 09:37</p>
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<p>1 obviousness of the asserted claims from the point of 09:37 2 view of a person of ordinary skill in the art. 09:37 3 Do you see that? 09:37 4 A Yes. 09:37 5 Q And the counsel you referred to there 09:37 6 is -- is defendants' counsel, I take it, correct? 09:37 7 A Yes. 09:37 8 Q And as you note in paragraph 25, you are 09:37 9 not a lawyer, correct? 09:37 10 A Correct. 09:37 11 Q So you relied upon defendants' counsel's 09:37 12 instructions regarding the legal standards for 09:37 13 obviousness, correct? 09:37 14 A Yes, in consultation with the lawyers. 09:37 15 Q Right. And the -- the legal standards 09:37 16 that you applied in formulating your opinions on 09:37 17 obviousness are set forth in paragraphs 26 to 31 of 09:37 18 your opening report, correct? 09:37 19 A Yes. 09:37 20 Q And the legal standard you used is the 09:37 21 legal standard that you set forth from counsel; you 09:37 22 didn't rely on your own independent understanding of 09:37 23 obviousness, correct? 09:38 24 A I -- I consulted with counsel, taking 09:38 25 advantage of their expertise, to provide my 09:38</p>	<p>1 understanding of what these concepts meant. 09:38 2 Q You -- in your opening report, you do not 09:38 3 express any opinions concerning the legal defense of 09:38 4 "anticipation," correct? 09:38 5 A I don't know what that means. Could you 09:38 6 redefine that question, please? 09:38 7 Q I -- you are -- do you have an 09:38 8 understanding of the legal defense of 09:38 9 "anticipation"? 09:38 10 A Of anticipation? I'm not recalling 09:38 11 anything about anticipation. 09:38 12 Q Okay. So -- 09:38 13 A I would have to do further research on -- 09:38 14 Q Okay. 09:38 15 A -- that point. 09:38 16 Q So to the best of your recollection, you 09:38 17 are not offering an opinion that the asserted claims 09:38 18 are invalid for anticipation, correct? 09:38 19 A Could you define what you mean by "for 09:38 20 anticipation"? 09:38 21 Q Well, I would like to ask the question 09:38 22 here. And if you don't understand anticipation, 09:39 23 that's fine. 09:39 24 Do you find that you can't answer the 09:39 25 question, whether or not you're offering an opinion 09:39</p>

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<p>1 Q (BY MR. SIPES) Can -- 02:04</p> <p>2 A Do you -- 02:04</p> <p>3 Q How would a person of ordinary skill in 02:04</p> <p>4 the art determine the effect of EPA alone on LDL 02:04</p> <p>5 cholesterol, given the results in Kurabayashi? 02:04</p> <p>6 A Well, what you can conclude in this study 02:04</p> <p>7 is that in a patient treated with estriol, that EPA 02:04</p> <p>8 intervention lowers the LDL cholesterol relative to 02:04</p> <p>9 a person who is taking estriol that didn't get the 02:04</p> <p>10 EPA. 02:04</p> <p>11 So in other words, this is -- for this 02:04</p> <p>12 specific population where both groups were treated 02:04</p> <p>13 with estriol, EPA lowers the LDL cholesterol in 02:04</p> <p>14 that -- in that particular -- 02:04</p> <p>15 Q And -- 02:04</p> <p>16 A -- group. 02:04</p> <p>17 Q -- and that's what I'm trying 02:04</p> <p>18 to understand -- so -- and I don't understand -- is 02:04</p> <p>19 it your testimony that the data in Kurabayashi 02:04</p> <p>20 suggests that the group that received EPA on top of 02:04</p> <p>21 estriol, saw greater reductions in LDL-C than the 02:04</p> <p>22 patients who only received estriol? 02:05</p> <p>23 MR. REIG-PLESSIS: Objection to form; 02:05</p> <p>24 mischaracterizes. 02:05</p> <p>25 A Yeah, I'm sorry. You're going to have to 02:05</p>	<p>1 say that again. 02:05</p> <p>2 Q (BY MR. SIPES) Is it your testimony that 02:05</p> <p>3 from Kurabayashi, the patients who received EPA on 02:05</p> <p>4 top of estriol, saw greater reductions in LDL-C than 02:05</p> <p>5 the control group that received estriol alone? 02:05</p> <p>6 MR. REIG-PLESSIS: Same objection. 02:05</p> <p>7 A I think what we can conclude is that both 02:05</p> <p>8 groups saw a significant decrease in LDL 02:05</p> <p>9 cholesterol. 02:05</p> <p>10 Q (BY MR. SIPES) And would the conclusion be 02:05</p> <p>11 from that that the estriol was decreasing the LDL 02:05</p> <p>12 cholesterol? 02:05</p> <p>13 A Not necessarily. And I have noticed in 02:05</p> <p>14 reviewing the papers for this that a lot of the 02:05</p> <p>15 studies, the LDL cholesterol levels tend to go down 02:05</p> <p>16 over time. 02:05</p> <p>17 That was observed in JELIS as well. And I 02:05</p> <p>18 have noticed that in many of the other studies. So 02:05</p> <p>19 there's -- there are other factors that can be 02:05</p> <p>20 affecting LDL cholesterol in this study. 02:06</p> <p>21 Q But -- but it's fair to say from the 02:06</p> <p>22 results presented in Kurabayashi that EPA did not, 02:06</p> <p>23 in a statistically significant way, reduce LDL-C 02:06</p> <p>24 cholesterol compared to control? 02:06</p> <p>25 A Okay. I'm having to look at the figure 02:06</p>
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<p>1 legend here, because I think this is a fairly 02:06</p> <p>2 technical point. 02:06</p> <p>3 Yes, okay, I think that's reasonable 02:06</p> <p>4 conclusion. It looks like there were similar 02:06</p> <p>5 reductions in LDL cholesterol in both groups. 02:06</p> <p>6 Q Right. Numerically, estriol alone reduced 02:06</p> <p>7 LDL-C to a greater extent than estriol plus EPA, 02:06</p> <p>8 correct? 02:07</p> <p>9 A Well -- 02:07</p> <p>10 MR. REIG-PLESSIS: Objection to form. 02:07</p> <p>11 A -- I think the correct interpretation is 02:07</p> <p>12 there's no statistical difference between the two 02:07</p> <p>13 groups. 02:07</p> <p>14 Q (BY MR. SIPES) Right. The -- which is to 02:07</p> <p>15 say the addition of EPA to estriol did not make any 02:07</p> <p>16 statistically significant difference on LDL-C? 02:07</p> <p>17 A I think it would be correct to say that in 02:07</p> <p>18 this particular study in these patients, yes. 02:07</p> <p>19 Q And the baseline triglycerides in the 02:07</p> <p>20 Kurabayashi study -- 02:07</p> <p>21 A I just want to -- some of these studies 02:07</p> <p>22 were in a subset, I believe. Is that correct or is 02:07</p> <p>23 that -- let me just look -- may I look at the 02:07</p> <p>24 text -- 02:07</p> <p>25 Q Sure. 02:07</p>	<p>1 A -- for a minute? Okay. 02:07</p> <p>2 This is the overall population, I believe, 02:08</p> <p>3 in this particular study. 02:08</p> <p>4 Q The -- the baseline triglycerides in 02:08</p> <p>5 Kurabayashi was 135.6 milligrams per deciliter for 02:08</p> <p>6 the EPA group, correct? 02:08</p> <p>7 A Yes. 02:08</p> <p>8 Q So those are normal triglyceride levels? 02:08</p> <p>9 A They're less than 150 milligrams per 02:08</p> <p>10 deciliter. 02:08</p> <p>11 Q So Kurabayashi was not conducted in a 02:08</p> <p>12 hypertriglyceridemic patient population? 02:08</p> <p>13 A No. 02:08</p> <p>14 Q If you'll turn to page 523, the right-hand 02:08</p> <p>15 column -- 02:09</p> <p>16 A Yes. 02:09</p> <p>17 Q -- there's a sentence that says, The 02:09</p> <p>18 proportion of cases showing improvement of 02:09</p> <p>19 triglyceride levels was 10 percent, 2 of 20, and 02:09</p> <p>20 55 percent of 11 of 20 respectively. 02:09</p> <p>21 Do you see that? 02:09</p> <p>22 A Boy, they -- they keep saying the same -- 02:09</p> <p>23 it's -- it's going to take me a minute because they 02:09</p> <p>24 keep repeating the same phraseology all the way 02:09</p> <p>25 through here. Can you repeat that one more time -- 02:09</p>

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<p>1 Q Yes. 02:09</p> <p>2 A -- for me? 02:09</p> <p>3 Q There's a reference to, The proportion of 02:09</p> <p>4 cases showing improvement of triglyceride levels was 02:09</p> <p>5 10 percent, 2 of 20, and 55 percent, 11 of, 20 02:09</p> <p>6 respectively. 02:09</p> <p>7 A Okay. Let me just review this. Yes. 02:09</p> <p>8 Q So at least for those patients that 02:10</p> <p>9 continued to the end of the study, 45 percent of 02:10</p> <p>10 them that were on EPA plus estriol did not see 02:10</p> <p>11 improvements in triglyceride levels, correct? 02:10</p> <p>12 A According to the criteria, they don't 02:10</p> <p>13 really define here what they mean by "improvement in 02:10</p> <p>14 triglyceride levels," and so I think that makes that 02:10</p> <p>15 statement somewhat ambiguous. 02:10</p> <p>16 Q So would a person of ordinary skill in the 02:10</p> <p>17 art in 2008 be able to understand that statement? 02:10</p> <p>18 A I think they would say there's -- appears 02:10</p> <p>19 to be a difference between the two groups, but we 02:10</p> <p>20 don't know exactly what that means because they 02:10</p> <p>21 don't define what they're talking about. 02:10</p> <p>22 Q For purposes of developing a treatment for 02:10</p> <p>23 very high triglycerides, what response rate would be 02:10</p> <p>24 desirable in the TG-lowering agent -- 02:10</p> <p>25 MR. REIG-PLESSIS: Objection to form. 02:10</p>	<p>1 Q (BY MR. SIPES) -- or what -- what response 02:10</p> <p>2 would be considered acceptable? 02:10</p> <p>3 MR. REIG-PLESSIS: Same objection. 02:10</p> <p>4 A I think, again, it's a very broad 02:11</p> <p>5 question. And I think that you would have to define 02:11</p> <p>6 more carefully what the clinical population was. 02:11</p> <p>7 You would have to give me additional 02:11</p> <p>8 information about what exact circumstances you're 02:11</p> <p>9 talking about. Are these diabetics? Nondiabetics? 02:11</p> <p>10 People with heart disease? People without heart 02:11</p> <p>11 disease? 02:11</p> <p>12 I think there's a lot of variables in that 02:11</p> <p>13 equation. 02:11</p> <p>14 MR. SIPES: I think this would be a good 02:11</p> <p>15 time for, among other things, a break. 02:11</p> <p>16 THE VIDEOGRAPHER: This marks the end of 02:11</p> <p>17 media file labeled No. 5. Off the record at 02:11</p> <p>18 2:12 p.m. 02:11</p> <p>19 (A break was taken from 2:12 p.m. to 02:11</p> <p>20 2:27 p.m.) 02:11</p> <p>21 THE VIDEOGRAPHER: This marks the 02:25</p> <p>22 beginning of media file labeled No. 6. Back on the 02:25</p> <p>23 record 2:27 p.m. 02:25</p> <p>24 Q (BY MR. SIPES) I'm going to hand you 02:26</p> <p>25 Exhibit 16. 02:26</p>
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<p>1 (Exhibit 16 was marked for identification 02:26</p> <p>2 and is attached to the transcript.) 02:26</p> <p>3 Q (BY MR. SIPES) Do you recognize Exhibit 16 02:26</p> <p>4 as U.S. Patent 8,293,728 that is at issue in this 02:26</p> <p>5 case? 02:26</p> <p>6 A Yes. 02:26</p> <p>7 Q And are you familiar with the practice of 02:26</p> <p>8 referring to a patent by its last three numbers? 02:26</p> <p>9 A I am. 02:26</p> <p>10 Q So would it be all right if we refer to 02:26</p> <p>11 Exhibit 16 at the '728 Patent? 02:26</p> <p>12 A Yes. 02:26</p> <p>13 Q Now, I want you to look at your reply 02:26</p> <p>14 report, Exhibit 3, paragraph 25. 02:26</p> <p>15 A So where am I looking now? 02:26</p> <p>16 Q Your reply report, paragraph 25. It's on 02:26</p> <p>17 page 7. 02:27</p> <p>18 A I'm trying to move the paper away from 02:27</p> <p>19 myself. Okay. Yes. 02:27</p> <p>20 Q In the first sentence of paragraph 25, you 02:27</p> <p>21 state, To be clear, under my definition, a POSA 02:27</p> <p>22 would have had a high level of skill relevant to the 02:27</p> <p>23 asserted patents. 02:27</p> <p>24 Do you see that? 02:27</p> <p>25 A Yes. 02:27</p>	<p>1 Q Why, in your opinion, would a person of 02:27</p> <p>2 ordinary skill in the art, for purposes of the 02:27</p> <p>3 asserted patents in this case, have had a high level 02:27</p> <p>4 of skill? 02:27</p> <p>5 A Well, I think evaluating whether or not 02:27</p> <p>6 something is actually significantly different -- in 02:27</p> <p>7 other words, if something really is a new invention 02:27</p> <p>8 versus what was present in the art before requires a 02:27</p> <p>9 fairly sophisticated knowledge of biochemistry and 02:27</p> <p>10 physiology. 02:27</p> <p>11 Q Do you think it would require a 02:27</p> <p>12 sophisticated knowledge of biochemistry and 02:27</p> <p>13 physiology -- 02:27</p> <p>14 A Not -- 02:27</p> <p>15 Q -- okay. Let's -- 02:28</p> <p>16 A -- I'm stopping. I'm stopping. 02:28</p> <p>17 Q Did you develop your -- your definition of 02:28</p> <p>18 a person of ordinary skill in the art based on what 02:28</p> <p>19 would be required to evaluate the patentability of 02:28</p> <p>20 the invention claimed in the asserted patents? 02:28</p> <p>21 MR. REIG-PLESSIS: Objection to form. 02:28</p> <p>22 A I think it would be required to evaluate 02:28</p> <p>23 the totality of the evidence that's supporting 02:28</p> <p>24 the -- the claims of the patent, would be my 02:28</p> <p>25 evaluation. 02:28</p>

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<p>1 Q (BY MR. SIPES) All right. And what sort 02:28</p> <p>2 of knowledge would be required to evaluate the 02:28</p> <p>3 evidence supporting the claims of the patents? 02:28</p> <p>4 A Well, I think we outline it here. I would 02:28</p> <p>5 probably pretty much stick with what the definition 02:28</p> <p>6 here is, as -- 02:28</p> <p>7 Q And -- 02:28</p> <p>8 A -- as outlined in paragraph 25. 02:28</p> <p>9 Q Okay. So that would require a knowledge 02:28</p> <p>10 of -- of lipid biochemistry, correct? 02:29</p> <p>11 MR. REIG-PLESSIS: Objection to form; 02:29</p> <p>12 mischaracterizes. 02:29</p> <p>13 A Yeah, I -- I think the way this is meant 02:29</p> <p>14 to explain it is -- is there could be different 02:29</p> <p>15 areas within this context -- in this definition. 02:29</p> <p>16 You wouldn't necessarily have to have every single 02:29</p> <p>17 one of these things. 02:29</p> <p>18 Q (BY MR. SIPES) Do you believe that you 02:29</p> <p>19 would need a medical degree? 02:29</p> <p>20 A I do not. 02:29</p> <p>21 Q Okay. If -- if a person didn't have a 02:29</p> <p>22 medical degree, what would they need to evaluate the 02:29</p> <p>23 evidence in the patent? 02:29</p> <p>24 A I think they would have to have extensive 02:29</p> <p>25 experience in the lipid field, practical experience. 02:29</p>	<p>1 They would have to have a detailed familiarity with 02:29</p> <p>2 the literature, and they would have to have some 02:29</p> <p>3 basic knowledge of pharmacology and biochemistry. 02:29</p> <p>4 Q And when you say to have "practical 02:29</p> <p>5 experience in the field," what -- if somebody wasn't 02:29</p> <p>6 a medical doctor, that experience would not involve 02:29</p> <p>7 treating patients, correct? 02:30</p> <p>8 A Well, that would not involve prescribing 02:30</p> <p>9 treatment for patients. 02:30</p> <p>10 Q Okay. 02:30</p> <p>11 A So for example, let's just imagine a Ph.D. 02:30</p> <p>12 They might not be able to write a prescription for 02:30</p> <p>13 treating a patient, but I know Ph.D.s in the field 02:30</p> <p>14 who are extremely knowledgeable about many, many 02:30</p> <p>15 different aspects of -- of this area and would be 02:30</p> <p>16 capable of making a very well-informed judgment. 02:30</p> <p>17 Q And would a person with a Ph.D. evaluating 02:30</p> <p>18 the evidence supporting the invention, consult with 02:30</p> <p>19 a physician or other medical doctor? 02:30</p> <p>20 A Not necessarily. I think, again, it 02:30</p> <p>21 depends on your experience. 02:30</p> <p>22 And as I'm learning in this -- this 02:30</p> <p>23 session right here with you guys, as well as my 02:30</p> <p>24 interactions with my team, lawyers can have a very 02:30</p> <p>25 good knowledge of what's going on in this area 02:30</p>
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<p>1 because they're extremely familiar with the 02:30</p> <p>2 literature and they know a lot of the wrinkles 02:31</p> <p>3 relevant to it. 02:31</p> <p>4 So I think it's really a matter of what 02:31</p> <p>5 exactly their knowledge is. 02:31</p> <p>6 Q Okay. But -- but you're not suggesting a 02:31</p> <p>7 person of ordinary skill in the art would need 02:31</p> <p>8 excess to a lawyer, I take it? 02:31</p> <p>9 A No. No. 02:31</p> <p>10 Q Yeah. Okay. You don't include within the 02:31</p> <p>11 skill set of the -- of the team to which a person of 02:31</p> <p>12 skill would have access, a biostatistician, I take 02:31</p> <p>13 it? 02:31</p> <p>14 MR. REIG-PLESSIS: Objection to form. 02:31</p> <p>15 A I think that would depend on the 02:31</p> <p>16 particular circumstances. And I -- really trying to 02:31</p> <p>17 specify every single thing that you need to 02:31</p> <p>18 understand these things depends on the precise 02:31</p> <p>19 circumstances of what's being evaluated and what's 02:31</p> <p>20 involved. 02:31</p> <p>21 So in some circumstances you -- you might 02:31</p> <p>22 need to have a very detailed evaluation of 02:31</p> <p>23 biostatistics. And for example, in my area -- one 02:31</p> <p>24 my areas of research, we do very large numbers of 02:31</p> <p>25 protein measurements in lipoproteins. 02:32</p>	<p>1 And since we're measuring so many 02:32</p> <p>2 different things in so many different people, trying 02:32</p> <p>3 to interpret that data would require someone with 02:32</p> <p>4 biostatistical expertise. And for example, we get 02:32</p> <p>5 that kind of expertise when we need it. 02:32</p> <p>6 On the other hand, if you're trying to 02:32</p> <p>7 interpret many clinical studies, I think that you 02:32</p> <p>8 don't necessarily need a strong biostatistical 02:32</p> <p>9 background. And even just taking it at more or less 02:32</p> <p>10 face value, the p-values. And assuming that they 02:32</p> <p>11 have a reasonable understanding of -- of statistics, 02:32</p> <p>12 what a p-value test is, what a -- what some of the 02:32</p> <p>13 standard tests are, that might be adequate. So it 02:32</p> <p>14 very much depends on the exact -- on the exact 02:32</p> <p>15 nature of what it is you are trying to -- to do. 02:32</p> <p>16 Q Okay. 02:32</p> <p>17 A I think it's a -- it's a complicated area. 02:32</p> <p>18 Q The patent describes a -- a clinical study 02:32</p> <p>19 of 4 grams of EPA, correct, in Column 13 -- 02:32</p> <p>20 MR. REIG-PLESSIS: Objection to form. 02:32</p> <p>21 Q (BY MR. SIPES) -- the -- the patent -- the 02:32</p> <p>22 '728 Patent? 02:32</p> <p>23 A I'm sorry? Where is that? 02:32</p> <p>24 Q It's Exhibit -- 02:32</p> <p>25 A Oh -- 02:33</p>

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<p>1 Q -- 16. 02:33</p> <p>2 A -- right in front of me. And correct me 02:33</p> <p>3 if I'm wrong here, but that would be under the 02:33</p> <p>4 claims? 02:33</p> <p>5 Q No. No. No. Column 13, the example. 02:33</p> <p>6 A Okay. Please restate the question. 02:33</p> <p>7 Q The -- the example describes a 02:33</p> <p>8 placebo-controlled, randomized, double-blind 12-week 02:33</p> <p>9 study with open-label extension conducted on EPA, 02:33</p> <p>10 correct? 02:33</p> <p>11 MR. REIG-PLESSIS: Objection to form; 02:33</p> <p>12 mischaracterizes. 02:33</p> <p>13 A I -- I think I would have to go with what 02:33</p> <p>14 the text says. It says a placebo -- a multicenter 02:33</p> <p>15 placebo -- it says what it says. I would go with 02:33</p> <p>16 the -- 02:33</p> <p>17 Q (BY MR. SIPES) Right. 02:33</p> <p>18 A -- text there. 02:33</p> <p>19 Q And "AMR101," do you understand the 02:33</p> <p>20 reference to "AMR101 in '728 Patent? 02:33</p> <p>21 A I do. 02:33</p> <p>22 Q And what is AMR101? 02:33</p> <p>23 A EPA -- 02:33</p> <p>24 Q That -- that's -- 02:33</p> <p>25 A -- ester -- 02:33</p>	<p>1 Q -- pure ester? 02:33</p> <p>2 A -- yeah, pure. 9 -- greater than 02:34</p> <p>3 96 percent pure EPA and ester of that form of the -- 02:34</p> <p>4 the -- 02:34</p> <p>5 Q And that -- 02:34</p> <p>6 A -- fatty acid. 02:34</p> <p>7 Q -- and the -- and what the patent is 02:34</p> <p>8 describing in the example is the administration of 02:34</p> <p>9 pure EPA to patients with fasting triglyceride 02:34</p> <p>10 levels of 500 and above, correct -- 02:34</p> <p>11 MR. REIG-PLESSIS: Objection to form. 02:34</p> <p>12 Q (BY MR. SIPES) -- 500 milligrams per 02:34</p> <p>13 deciliter above, correct? 02:34</p> <p>14 MR. REIG-PLESSIS: Same objection. 02:34</p> <p>15 A Well, I can quote what it says, With 02:34</p> <p>16 fasting triglyceride levels of greater than or equal 02:34</p> <p>17 to 500 milligrams per deciliter and less than or 02:34</p> <p>18 equal to 1,500 milligrams per deciliter with 02:34</p> <p>19 definitions provided as well in millimoles per 02:34</p> <p>20 liter. 02:34</p> <p>21 Q (BY MR. SIPES) So would a person of 02:34</p> <p>22 ordinary skill in the art in light of the study 02:34</p> <p>23 described there, do you believe that would require 02:34</p> <p>24 consultation with a biostatistician to interpret the 02:34</p> <p>25 results of that study? 02:34</p>
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<p>1 MR. REIG-PLESSIS: Objection to form and 02:34</p> <p>2 as to "results." 02:34</p> <p>3 A I mean, there's a lot of things that are 02:35</p> <p>4 missing from this particular statement. So again, 02:35</p> <p>5 you're making some very broad statements. 02:35</p> <p>6 You don't specify what the number of 02:35</p> <p>7 subjects studied is going to be. You don't discuss 02:35</p> <p>8 what your power calculations are. You don't specify 02:35</p> <p>9 what you're going to consider significant and 02:35</p> <p>10 nonsignificant. So this is -- I mean, this is sort 02:35</p> <p>11 of a very bare-bones description of what -- what you 02:35</p> <p>12 would really need to do to evaluate that. 02:35</p> <p>13 Q So when you were defining your person of 02:35</p> <p>14 ordinary skill in the art, were you taking into 02:35</p> <p>15 account the skill that would be necessary to 02:35</p> <p>16 evaluate the results? 02:35</p> <p>17 A Yes. 02:35</p> <p>18 Q Okay. And in your view, that would 02:35</p> <p>19 require a high level of skill? 02:35</p> <p>20 A No. In my view, it would require more 02:35</p> <p>21 information and an adequate technical background. 02:35</p> <p>22 It -- and again, you're making very broad 02:35</p> <p>23 statements here, and I think the issue very much 02:35</p> <p>24 depends on the particulars. 02:35</p> <p>25 And I'll also add that just achieving 02:35</p>	<p>1 statistical significance does not necessarily mean 02:36</p> <p>2 it's clinically significant. Right. 02:36</p> <p>3 So I think, again, that requires judgment 02:36</p> <p>4 about what the overall context in the field is and 02:36</p> <p>5 what a significant improvement would be. 02:36</p> <p>6 Q And would -- judgments about the clinical 02:36</p> <p>7 significance of the results, that would require a 02:36</p> <p>8 medical degree? 02:36</p> <p>9 A Not necessarily. I think -- I know 02:36</p> <p>10 Ph.D.s. I have worked with Ph.D.s that I felt were 02:36</p> <p>11 qualified to make that kind of a judgment. 02:36</p> <p>12 Q And -- 02:36</p> <p>13 A And I will mention in passing: I know 02:36</p> <p>14 M.D.s that are not qualified to make that kind of a 02:36</p> <p>15 judgment, so I don't think it's really whether you 02:36</p> <p>16 have a Ph.D. or an M.D. Yeah. 02:36</p> <p>17 Q Did you, in -- in determining what the 02:36</p> <p>18 skill level is "of a person of ordinary skill," 02:36</p> <p>19 evaluate the level of skill of the inventors named 02:36</p> <p>20 on the patent? 02:36</p> <p>21 A I did not. 02:36</p> <p>22 Q Okay. Do you know the skill level of the 02:37</p> <p>23 inventors named on the patent? 02:37</p> <p>24 A I do not. 02:37</p> <p>25 Q Okay. At this time in March of 2008, do 02:37</p>

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4 I, JAY W. HEINECKE, M.D., do hereby declare
5 under penalty of perjury that I have read the
6 foregoing transcript; that I have made any
7 corrections as appear noted, in ink, initialed by
8 me, or attached hereto; that my testimony as
9 contained herein, as corrected, is true and correct.

10 EXECUTED this_____ day of_____,
11 20____, at_____, _____.
(City) (State)

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14 _____
15 JAY W. HEINECKE, M.D.
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1 I, MARY J. GOFF, CSR No. 13427, Certified
2 Shorthand Reporter of the State of California,
3 certify;

4 That the foregoing proceedings were taken
5 before me at the time and place herein set forth, at
6 which time the witness declared under penalty of
7 perjury; that the testimony of the witness and all
8 objections made at the time of the examination were
9 recorded stenographically by me and were thereafter
10 transcribed under my direction and supervision; that
11 the foregoing is a full, true, and correct
12 transcript of my shorthand notes so taken and of the
13 testimony so given;

14 That before completion of the deposition,
15 review of the transcript (XX) was () was not
16 requested: () that the witness has failed or
17 refused to approve the transcript.

18 I further certify that I am not financially
19 interested in the action, and I am not a relative or
20 employee of any attorney of the parties, nor of any
21 of the parties.

22 I declare under penalty of perjury under the
23 laws of California that the foregoing is true and
24 correct, dated this 30th day of July, 2019.

Mary J. Goff

25 MARY GOFF

Amarin Pharma Inc. et al. v. Hikma Pharmaceuticals USA Inc. et al., No. 2:16-cv-02525-MMD-NJK (D. Nev.)

Deposition of Jay W. Heinecke, M.D., July 17, 2019

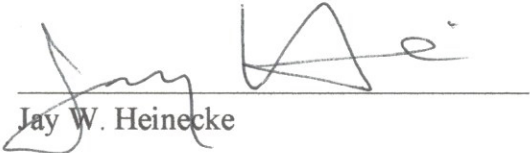
I wish to make the following changes, for the following reasons:

PAGE:LINE	CHANGE FROM	CHANGE TO	REASON
10:1	I'm currently provide by the	I'm currently a <u>professor</u> at the	Transcription error
17:4	somebody at Bud Barner	somebody at <u>Budd Larner</u>	Transcription error
48:19	biochemists in the n-3 (indiscernible) positions in the medical	biochemists <u>and the omega-3</u> in the medical	Transcription error
68:19-20	It's manifested by the lack of protein particles	It's manifested by the lack of <u>lipoprotein</u> particles	Transcription error
114:15	For raising LDL-C cholesterol	For raising LDL-C cholesterol?	Transcription error
114:25	deflecting IDL and LDL.	<u>affecting</u> IDL and LDL.	Transcription error
190:11	there was a whole nother contingent	there was a whole <u>other</u> contingent	Transcription error
193:2	forward as for -- as -- as well	forward [delete for -- as -- as] as well.	Transcription error
197:13-14	study as a	study <u>has</u> a	Transcription error
215:9	buying a gen --	buying a <u>generic</u>	Transcription error
227:1	certainly an HDL --	certainly an HDL <u>expert</u> ,	Transcription error
229:2-3	at hand here, whereas DHA did not.	at hand here, whereas <u>EPA</u> did not.	Transcription error
252:8	has a value of 233 with	has a value of <u>300</u> with	Conform to facts
261:25	and what you should synch.	and what you should <u>use</u> .	Transcription error
287:22	B R U N N E L [sic]	<u>B R U N Z Z E L</u>	Transcription error
296:9	for example, is plat --	for example, is <u>plasmapheresis</u>	Transcription error
297:14	get erupted xanthomas	get <u>eruptive</u> xanthomas	Transcription error
333:9	of "whoa" where	of <u>woes</u> where	Transcription error

PAGE:LINE	CHANGE FROM	CHANGE TO	REASON
343:21	synth -- synth statin-treated patients	<u>simvastatin</u> -treated patients	Transcription error
347:8	increase LD -- actually	increase <u>LDL-cholesterol</u> actually	Transcription error

I, Jay W. Heinecke, do hereby certify that I have read the transcript of my deposition and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance noted above.

Dated: Aug 14, 2019


Jay W. Heinecke